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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/629,596	07/31/2000	Michael J. Adang	UGR-100X	4280

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EXAMINER

PONNALURI, PADMASHRI

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 10/20/2003

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/629,596

Applicant(s)

ADANG ET AL.

Examiner

Padmashri Ponnaluri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 6-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's election without traverse of group I, claims 1-5, filed on 2/24/03 in Paper No. 21 is acknowledged.
2. Applicant's election without traverse of CryIAc toxin and cp IIIphage coat protein , and the fusion protein sequence of SEQ ID NO: 8, filed on 8/6/03, in Paper No. 23 is acknowledged.
3. Claims 6-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 21.
4. Claims 1-5 are currently being examined in this application.
5. The preliminary amendments to comply the sequences in the specification with sequence rules have been considered and entered into the application.

Priority

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification of in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Information Disclosure Statement

6. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Oath/Declaration

The oath/declaration filed on 10/23/00 has been fully considered and entered into the application.

Drawings

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the nucleic acid sequences encoding the fusion proteins of the instant claims must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is written description rejection.

The instant claims briefly recite a polynucleotide molecule that comprises a nucleotide sequence encoding an active toxin and a nucleotide sequence encoding a phage vector protein.

The specification disclosure is drawn to *Bacillus thuringiensis* (Bt) toxins. The specification discloses that the Bt protein toxin and fusion proteins which have toxic activity. The specification does not disclose the nucleic acid sequence encoding the fusion proteins of Bt toxin and the phage coat proteins. The specification does not disclose nucleic acid encoding any other fusion proteins of a toxin and a phage coat protein. The specification examples are drawn to the use of specific M13 phage vectors fUSE5 and ASurfZap to prepare the (Bt toxin Cry 1Ac and phage coat protein) fusion proteins and display on the surface of the phage. The specification description clearly does not provide adequate representation regarding the open ended product (polynucleotide molecule) of the instant claims.

With regard to the description requirement, Applicants' attention is directed to The Court of Appeals for the Federal Circuit which held that "written description of an invention involving a chemical genus, like a description a chemical species, 'requires precise definition, such as structure or formula or chemical name' of an the claimed subject matter sufficient to distinguish

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it from other materials.” *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1405 (1997), quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1601 (Fed. Cir. 1993) [the claims at issue in *University of California v. Eli Lilly* defined the invention by function of the claimed DNA].

This holding is applicable to the present claimed product or nucleic acid molecule encoding the fusion protein of Bt toxin and phage coat protein because the invention lacks showing of sufficient identifying characteristics or lacks examples of claimed product (polynucleotide molecule encoding the fusion protein) to demonstrate possession of claimed generic.

The specification examples are drawn to fusion proteins of Cry 1Ac (Bt toxin protein) and phage coat proteins and display of the proteins on the phage surface. Thus the specification lacks written description of polynucleotide encoding any toxin and phage coat protein as claimed in the present invention.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention..

Claim 5 recites a polynucleotide molecule of claim 1 (comprises a nucleotide sequence encoding an active toxin and a nucleotide sequence encoding a phage vector protein) that encodes a fusion protein as shown in figure 1.

The figure 1 in the drawings has peptide sequences of fUSES construct and SurfZap construct. The sequence listing recites that SEQ ID NO: 7 are C-terminus amino acid sequence

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of Cry 1Ac; and SEQ ID NO: 8 are N-terminus of Cry 1Ac from figure 1. Figure 1 has nucleic acid encoding fusion proteins of SEQ ID NO: 9-14. Thus figure 1 does not have all the fusion proteins as the instant claim recites. Applicants are requested to amend the claim to recite the nucleic acid sequences encoding the specific fusion proteins.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Marzari et al (FEBS Letters, 411, 1997, pages 27-31).

The instant claims recite a polynucleotide molecule that comprises a nucleotide sequence encoding an active toxin and a nucleotide sequence encoding a phage vector protein.

Marzari et al disclose Phage display of *Bacillus thuringiensis* Cry 1A insecticidal toxin. The reference discloses display of different Cry 1A toxin regions on the surface of the phagemids using the display vector. The reference discloses that cloning of Cry 1A toxin fragment and expression of the fusion protein on the phage coat (refers to ‘...fusion proteindisplayed on the surface of the phage.’ of the instant claims) (i.e., see page 27 left column). The reference discloses that the fusion protein between the Cry 1A protein and GST or gene III (refers to the phage vector protein of the instant claims) (i.e., see materials and methods). The reference discloses the sequence of N-terminal region of the Bt toxin (i.e., see figure 1). The

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reference discloses that the vectors pGEX-BtD11 and pGEX-Bt12 express the fusion protein.

The reference clearly anticipates the claimed nucleic acid encoding the fusion proteins.

14. Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Kasman et al (Applied and Environmental Microbiology, Aug 1998, vol. 64, No. 8, pages 2995-3003).

The instant claims recite a polynucleotide molecule that comprises a nucleotide sequence encoding an active toxin and a nucleotide sequence encoding a phage vector protein.

Kasman et al disclose phage display of biologically active *Bacillus thuringiensis* toxin. The reference discloses that the activated *B. thuringiensis* toxin Cry 1Ac can be expressed in *E. coli* as a translational fusion with the minor phage coat protein of filamentous phage. The reference discloses the entire sequence of the modified Cry 1Ac gene and the phage gene pIII fusion was constructed and verified by DNA sequencing. Figure 1 discloses the amino acid sequences of Cry 1Ac derived from their DNA sequences. Figure 1 discloses the sequences of fusion proteins. Thus the reference clearly anticipates the claimed invention).

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 703-305-3884. The examiner is on Flex Schedule and can normally be reached on Monday through Friday from 7 AM and 3.30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

Pp
16 October 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER